IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

ACTELION PHARMACEUTICALS LTD and ACTELION PHARMACEUTICALS US, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Civil Action No. 1:23-cv-00088-TSK

ANSWER AND AFFIRMATIVE DEFENSES TO COMPLAINT

Mylan Pharmaceuticals Inc. ("MPI" or "Defendant"), by its undersigned attorneys, answers and responds to the Complaint for Patent Infringement of Plaintiffs Actelion Pharmaceuticals Ltd. and Actelion Pharmaceuticals US, Inc. (collectively, "Actelion" or "Plaintiffs"), as follows:

RESPONSE TO ALLEGATIONS PERTAINING TO THE PARTIES

1. Plaintiff Actelion Ltd is a Swiss corporation having a primary place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 1 and, therefore, denies those allegations.

2. Plaintiff Actelion Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 2 and, therefore, denies those allegations.

3. Upon information and belief, Defendant Mylan is a corporation organized and existing under the laws of West Virginia, with a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505.

ANSWER: MPI admits that it is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505.

RESPONSE TO ALLEGATIONS PERTAINING TO JURISDICTION AND VENUE

4. This is a civil action for infringement of United States Patent Nos. 7,094,781 ("the '781 patent") and 10,946,015 ("the '015 patent") (collectively, "the patents-in-suit"). This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MPI admits that the Complaint purports to be a patent infringement action alleging infringement of United States Patent Nos. 7,094,781 ("the'781 patent") and 10,946,015 ("the '015 patent") pursuant to the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*. MPI denies that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. MPI denies the remaining allegations set forth in paragraph 4.

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201-02, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MPI admits that the Complaint purports to be an action arising under 28 U.S.C. §§ 1331 and 1338(a) and 35 U.S.C. § 271. MPI denies the remaining allegations set forth in paragraph 5.

6. Upon information and belief, Mylan develops, manufactures, markets, distributes, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

ANSWER: MPI admits that MPI is a pharmaceutical company that develops, manufactures and distributes drug products. MPI does not contest personal jurisdiction in this action. MPI denies the remaining allegations set forth in paragraph 6.

7. Upon information and belief, Mylan is registered to do business in the State of West Virginia under Organization Number 20402.

ANSWER: Admitted.

8. Upon information and belief, Mylan is registered as a drug manufacturer with the West Virginia Board of Pharmacy under License No. MR0552262 and as a drug wholesaler under License No. WD0559319.

ANSWER: MPI admits that MPI is registered with the West Virginia Board of Pharmacy as a Manufacturer under license number MR0552262. MPI also admits that MPI is registered with the West Virginia Board of Pharmacy as a Wholesale Distributor under license number WD0559319. MPI denies the remaining allegations set forth in paragraph 8.

9. This Court has personal jurisdiction over Mylan because, *inter alia*, Mylan: (1) is incorporated in the State of West Virginia; (2) has its principal place of business in this Judicial District; (3) has purposely availed itself of the privilege of doing business in the State of West Virginia, including by, *inter alia*, registering to do business in the State of West Virginia under Organization No. 20402, and securing with the West Virginia Board of Pharmacy a drug manufacturer's license (License No. MR0552262) and a drug wholesaler's license (LicenseNo. WD0559319); (4) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District; (5) directly or indirectly maintains pervasive, continuous, and systematic contacts with this Judicial District, including the marketing, distribution, and/or sale of generic pharmaceutical products in this Judicial District; (6) upon information and belief, derives substantial revenue from the sale of its products in the State of West Virginia; and (7) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego market, sell, or distribute the ANDA Product throughout the United States, including in the State of West Virginia.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MPI does not contest personal jurisdiction in this action. MPI denies the remaining allegations set forth in paragraph 9.

10. This Court also has personal jurisdiction over Mylan because, *inter alia*, Mylan has committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent

infringement, including acts in the State of West Virginia, that have led to foreseeable harm and injury to Actelion in the State of West Virginia.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MPI does not contest personal jurisdiction in this action. MPI denies the remaining allegations set forth in paragraph 10.

11. This Court also has personal jurisdiction over Mylan because, *inter alia*, it has availed itself of the legal protections of the State of West Virginia by previously consenting to personal jurisdiction as well as asserting counterclaims in this Judicial District. *See*, *e.g.*, *Abraxis Bioscience, LLC v. Mylan Pharmaceuticals Inc.*, 23-cv-0033-TSK; *Novo Nordisk Inc. et al. v. Viatris Inc. et al.*, 23-cv-0013-TSK; *Bausch Health Ireland Limited et al. v. Mylan Pharmaceuticals Inc.*, 22-cv-0085-TSK; *Bayer Pharma AG, et al. v. Mylan Pharmaceuticals Inc. et al.*, 22-cv-0063-JPB; *AstraZeneca AB et al. v. Mylan Pharmaceuticals Inc. et al.*, 22-cv-0035-JPB-RWT.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MPI does not contest personal jurisdiction in this action. MPI denies the remaining allegations set forth in paragraph 11.

12. Venue is proper in this Court as to Mylan under 28 U.S.C. §§ 1391(b), (c),and/or (d), and 1400(b) because, *inter alia*, Mylan is incorporated in the State of West Virginia, has a principal place of business in this Judicial District, and has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons setforth above, and for other reasons that will be presented to the Court if such venue is challenged.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MPI does not contest venue in this Judicial District in this action, and MPI denies the remaining allegations set forth in paragraph 12.

RESPONSE TO ALLEGATIONS PERTAINING TO THE PATENTS-IN-SUIT

13. Actelion Inc. holds approved New Drug Application ("NDA") No. 204410, under which the FDA granted approval on October 18, 2013 for macitentan 10 mg oral once-a-day tablets, marketed in the United States under the trade name OPSUMIT®.

ANSWER: MPI admits that Actelion Pharmaceuticals US Inc. is listed in FDA's Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") as the holder of NDA No. 204410. MPI further admits that FDA's Orange Book

lists an approval date of October 18, 2013 for OPSUMIT® (macitentan), 10 mg oral tablets. MPI further admits that the prescribing information for OPSUMIT® (macitentan) (revised 06/2023) states that the dosage is 10 mg once daily. MPI denies the remaining allegations set forth in paragraph 13.

14. OPSUMIT® (macitentan), approved in NDA No. 204410, is indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

ANSWER: MPI admits that the prescribing information for OPSUMIT® (macitentan) (revised 06/2023) states that OPSUMIT is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH. MPI denies the remaining allegations set forth in paragraph 14.

15. Actelion Inc. markets and sells OPSUMIT® in the United States.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 15 and, therefore, denies those allegations.

16. Actelion Ltd owns the '781 patent, titled "Sulfamides and Their Use as Endothelin Receptor Antagonists." The '781 patent duly and legally issued on August 22, 2006. A copy of the '781 patent is attached as Exhibit A.

ANSWER: MPI admits that Plaintiffs purport to attach a copy of the '781 patent to the Complaint as Exhibit A, which speaks for itself and is the best source for its content. MPI further admits that the face of the '781 patent indicates that it issued on August 22, 2006 and is entitled "Sulfamides and Their Use as Endothelin Receptor Antagonists." MPI denies that the '781 patent was "duly and legally" issued. MPI is without sufficient knowledge and information to form a

belief as to the remaining allegations set forth in paragraph 16, and, on that basis, denies those allegations.

17. Actelion Ltd owns the '015 patent, titled "Stable Pharmaceutical Compositions Comrpising [sic] a Pyrimidine-Sulfamide." The '015 patent duly and legally issued on March 16, 2021.A copy of the '015 patent is attached as Exhibit B.

ANSWER: MPI admits that Plaintiffs purport to attach a copy of the '015 patent to the Complaint as Exhibit B, which speaks for itself and is the best source for its content. MPI further admits that the face of the '015 patent indicates that it issued on March 16, 2021 and is entitled "Stable Pharmaceutical Compositions Comprising a Pyrimidine-Sulfamide." MPI denies that the '015 patent was "duly and legally" issued. MPI is without sufficient knowledge and information to form a belief as to the remaining allegations set forth in paragraph 17, and, on that basis, denies those allegations.

18. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book"), as covering Actelion's OPSUMIT® brand macitentan tablets.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MPI admits that the '781 and '015 patents are listed in FDA's Orange Book for OPSUMIT® (macitentan). MPI denies the remaining allegations set forth in paragraph 18.

RESPONSE TO ALLEGATIONS PERTAINING TO ACTS GIVING RISE TO THE ACTION

19. Upon information and belief, Mylan has submitted Abbreviated New Drug Application ("ANDA") No. 211161 to the Food and Drug Administration ("FDA"), seeking FDA approval for the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of generic macitentan 10 mg oral tablets ("the ANDA Product").

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, MPI admits that it filed ANDA No. 211161 seeking

FDA approval for its proposed ANDA product. MPI denies the remaining allegations set forth in paragraph 19.

20. Mylan sent letters ("Notice Letters") with respect to the patents-in-suit to Actelion, stating that Mylan filed ANDA No. 211161, seeking approval from the FDA to commercially manufacture, use, or sell the ANDA Product in the United States (including, upon information and belief, in the State of West Virginia) prior to the expiration of the patents-in-suit.

ANSWER: MPI admits that it sent Notice Letters identifying the patents-in-suit notifying Actelion that MPI submitted ANDA No. 211161 seeking FDA approval for its proposed ANDA product prior to expiration of the patents-in-suit. The Notice Letters speak for themselves and are the best source for their content. MPI denies the remaining allegations set forth in paragraph 20.

21. The Mylan Notice Letters represented that ANDA No. 211161 included certifications under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certifications") with respect to the patents-in-suit.

ANSWER: MPI admits that its ANDA No. 211161 includes a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) regarding the patents-in-suit and that the Notice Letters so-notified Actelion. The Notice Letters speak for themselves and are the best source for their content. MPI denies the remaining allegations set forth in paragraph 21.

22. Upon information and belief, Mylan filed or caused to be filed ANDA No. 211161 with the FDA.

ANSWER: Admitted.

23. Separate and apart from certain contentions regarding patent validity, Mylan's Notice Letter with respect to the '781 patent does not identify any factual basis for, or any opinion of, noninfringement of Claims 1, 5-9, and 11 of that patent.

ANSWER: MPI admits that its Notice Letter with respect to the '781 patent contains a detailed statement of the factual and legal bases for MPI's Paragraph IV certification pursuant to Section 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug, and Cosmetic Act, and refers to the Notice

Letter for the contents thereof, except to state that the allegations inconsistent with the express terms of the document are denied. MPI denies the remaining allegations in Paragraph 23.

24. The ANDA Product for which Mylan seeks FDA approval in ANDA No. 211161 includes macitentan 10 mg as the active ingredient.

ANSWER: MPI admits that its proposed ANDA product that is the subject of ANDA No. 211161 includes macitentan 10 mg as the active ingredient. MPI denies the remaining allegations in Paragraph 24.

25. The chemical name of the compound macitentan is one of the chemical names recited in Claim 11 of the '781 patent.

ANSWER: MPI admits that the '781 patent speaks for itself and is the best source for its content. To the extent further allegations in paragraph 25 are not addressed by the foregoing, MPI denies them.

26. Separate and apart from certain contentions regarding patent validity, Mylan's Notice Letter with respect to the '015 patent does not identify any factual basis for, or any opinion of, noninfringement of Claims 1-2, 4, 10, 12, 14, 16-17, 22-36, and 38-42 of that patent.

ANSWER: MPI admits that its Notice Letter with respect to the '015 patent contains a detailed statement of the factual and legal bases for MPI's Paragraph IV certification pursuant to Section 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug, and Cosmetic Act, and refers to the Notice Letter for the contents thereof, except to state that the allegations inconsistent with the express terms of the document are denied. MPI denies the remaining allegations in Paragraph 26.

27. Actelion commenced this action within 45 days of the date of Actelion's receipt of Mylan's Notice Letter with respect to the '781 patent.

ANSWER: MPI admits that it sent the Notice Letter regarding MPI's ANDA No. 211161 and the '781 patent to Actelion Pharmaceuticals US, Inc. and Actelion Pharmaceuticals Ltd. on September 27, 2023, and Plaintiffs filed suit on November 7, 2023. MPI denies the remaining allegations in Paragraph 27.

RESPONSE TO ALLEGATIONS PERTAINING TO INFRINGEMENT

28. Actelion re-alleges paragraphs 1-27 as if fully set forth herein.

ANSWER: MPI reasserts and incorporates by reference its responses to paragraphs 1-27 above as if fully set forth herein.

29. By seeking approval of ANDA No. 211161 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit, Mylan has infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

30. Upon information and belief, Mylan was aware that the submission of ANDA No. 211161 that included the Paragraph IV Certifications with respect to the patents-in-suit to the FDA constituted an act of infringement of the patents-in-suit.

ANSWER: Denied.

31. Actelion is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of ANDA No. 211161 be a date that is not earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Actelion is or becomes entitled.

ANSWER: Denied.

32. If Mylan commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States, the ANDA Product prior to the expiration of the patents-in-suit, Mylan would further infringe the patents-in-suit under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

33. Upon information and belief, Mylan was aware that the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the ANDA Product before the expiration of the patents-in-suit would constitute an act of infringement of the patents-in-suit.

ANSWER: Denied.

34. Actelion is entitled to a declaration that, if Mylan commercially manufactures, uses, offers for sale, or sells the ANDA Product within the United States, imports the ANDA Product into the United States, and/or induces or contributes to such conduct, Mylan will infringe the patents-in-suit under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

35. Actelion will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court. Actelion does not have an adequate remedy at law.

ANSWER: Denied.

* * *

Any allegation in the Complaint and documents purported to be incorporated therein not specifically admitted in the paragraphs above is denied.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE: FAILURE TO STATE A CLAIM

The Complaint fails to state a claim upon which relief can be granted. The Complaint at least fails to state a cause of action under 35 U.S.C. § 271(a), (b), (c) and/or (g) against Mylan because Actelion has not plead with particularity facts regarding any post-ANDA approval activities.

SECOND AFFIRMATIVE DEFENSE: INVALIDITY OF U.S. PATENT NO. 7,094,781

The claims of the '781 patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, particularly §§ 101, 102, 103 and 112, as well as judicially created conditions for patentability, including obviousness-type double patenting, at least for the reasons set forth in MPI's September 27, 2023, Notice Letter.

THIRD AFFIRMATIVE DEFENSE: INVALIDITY OF U.S. PATENT NO. 10,946,015

The claims of the '015 patent are invalid for failure to meet one or more of the conditions for patentability specified in Title 35 of the United States Code, particularly §§ 101, 102, 103 and 112 at least for the reasons set forth in MPI's August 16, 2023, and August 28, 2023, Notice Letters.

FOURTH AFFIRMATIVE DEFENSE: NONINFRINGEMENT OF U.S. PATENT NO. 7,094,781

Mylan has not infringed, induced infringement of, or contributed to the infringement of,

and Mylan will not infringe, induce infringement of, or contribute to the infringement of, either literally or under the doctrine of equivalents, any valid and enforceable asserted claim of the '781 patent.

FIFTH AFFIRMATIVE DEFENSE: NONINFRINGEMENT OF U.S. PATENT NO. 10,946,015

Mylan has not infringed, induced infringement of, or contributed to the infringement of, and Mylan will not infringe, induce infringement of, or contribute to the infringement of, either literally or under the doctrine of equivalents, any valid and enforceable asserted claim of the '015 patent.

SIXTH AFFIRMATIVE DEFENSE: NO IMMEDIATE CASE OR CONTROVERSY

The Court does not have subject matter jurisdiction over any claim by Actelion under 35 U.S.C. § 271(a)-(c), because there is no real and immediate case or controversy.

SEVENTH AFFIRMATIVE DEFENSE: NO EXCEPTIONAL CASE

Neither the filing of MPI's ANDA No. 211161 nor the defense of this action gives rise to an exceptional case under 35 U.S.C. § 285.

EIGHTH AFFIRMATIVE DEFENSE: RESERVATION OF RIGHTS

Mylan's asserted affirmative defenses are based on information available and accessible to it at this time. Mylan's investigation of its defenses will continue throughout discovery in this matter and it reserves the right to supplement and/or amend these defenses.

ACTELION'S PRAYER FOR RELIEF

Mylan denies that Actelion is entitled to any relief sought in its Prayer for Relief requested in its Complaint.

REQUEST FOR RELIEF

WHEREFORE, MPI respectfully requests that this Court enter judgment:

` (a) dismissing the Complaint with prejudice and denying each and every prayer for relief contained therein;

(b) declaring that MPI's proposed ANDA product does not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '781 and '015 patents;

(c) declaring that the claims of the '781 and '015 patents are invalid;

(d) declaring that Actelion is not entitled to any injunctive remedy for the '781 and '015 patents;

(e) enjoining Actelion and its respective officers, employees, agents, representatives, attorneys and others acting on its behalf, from representing to anyone, either directly or indirectly, that MPI's proposed ANDA products have infringed, are infringing or will infringe, directly or indirectly, literally or under the doctrine of equivalents, any claim of the '781 and '015 patents;

(f) awarding MPI its costs;

(g) declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding MPI its attorneys' fees; and

(h) awarding to MPI such further relief as this Court may deem necessary, just and proper.

Respectfully submitted this 22nd day of March, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of March 2024, I served the foregoing "Answer and Affirmative Defenses to Complaint" by electronically filing the same with the clerk of the Court using the CM/ECF system, which will send electronic notice thereof to all counsel of record.

/s/ Gordon H. Copland

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